REMARKS/ARGUMENTS

The Applicants wish to thank the Examiner for her time in conducting a phone interview on September 11, 2002.

Claims 1, 4-35, 45-47 are pending in this application. Claims 36-44 have been withdrawn because they are to a non-elected invention. Applicants retain the right to file a divisional application to any cancelled or withdrawn claims. Claims 1, 4-7, 9, 11, 13, 15, 17, 18, 20, 22, 24-29, 45, and 46 have been amended to clarify the scope of the claims. Support for the claim amendments appears on page 7, line 25. The specification refers to a dose or amount that "produces a satisfactory immune response." Additional support for claim amendments appears on page 29, line 23 of the specification, which refers to "immunoprophylatic" protection of cysteine proteases. On page 30, line 8 of the specification, cysteine protease peptides are referred to as "immunogens." Attached hereto is a marked-up version of the changes made to the specification as Appendix A. Also attached hereto is a marked-up version of the changes made to the claims as Appendix B. Applicants have also included a copy of all pending claims as Appendix C. A marked up copy of amended drawings is included as Appendix D.

This issues outstanding in this application are as follows:

- Claims 1, 4-35, 45-47 have been rejected under 35 U.S.C. § 112 as allegedly lacking adequate written description.
- Claims 20-35, and 45-47 have been rejected for allegedly incorporating new matter.
- Claims 1, 4-35, 45-47 have been rejected under 35 U.S.C. § 112 as allegedly lacking adequate enabling description.
- The Examiner has requested support for the conservation of cysteine proteases.

I. Claims 1, 4-35, 45-47 are supported by the written description.

Examiner has rejected claims 1, 4-35, 45-47 due to a lack of adequate written description. The Examiner observes that the written description sets forth the creation of mutated cysteine proteases, which disrupt cysteine protease activity. The written description also includes methods for mapping antigenic domains. The Examiner remarks that the written description does not include the use of said mutated cysteine proteases in vaccines, or the use of cysteine proteases with a combination of mutations. The Applicants respectfully traverse.

Claims 1, 4-7, 9, 11, 13, 15, 17, 18, 20, 22, 24-29, 45, and 46 have been amended without prejudice and without acquiescence. The phrase "vaccine" has been replaced with "immunological composition." The phrase "confer immunity" has been replaced with "produce an immune response." The phrase "method of immunizing" has been replaced with "method of producing an immune response." Support for the claim amendments appears on page 7, line 25. The specification refers to a dose or amount that "produces a satisfactory immune response." Additional support for claim amendments appears on page 29, line 23 of the specification, which refers to "immunoprophylatic" protection of cysteine proteases. On page 30, line 8 of the specification, cysteine protease peptides are referred to as "immunogens."

The Examiner asserts that the specification does not support a vaccine, a method of conferring immunity, method of immunizing, or a method of producing an immune response. The above amendments eliminate the language that the Examiner contends is not adequately described in the specification. In light of the above amendments, Applicants respectfully request withdrawal of 35 U.S.C. § 112 written description rejection.

II. Claims 20-35, and 45-47 are supported by the specification, and do not incorporate new matter.

The Examiner asserts that added claims 20-35, and 45-47, which describe cysteine proteases containing at least one amino acid substitution constitute new matter. Applicants respectfully traverse.

Applicants assert that the application on pages 32, line 16, describes the method for

the creation of the genus of mutated cysteine proteases. Both site-directed and random mutagenesis techniques are described. Figure 8 describes the specific amino acid substitutions at positions 145, 185, 192, 340, 356, and 357, referred to in the specification on page 32, line 20. On page 32, line 16, the mutagenesis scheme is described as creating mutants which "(i) disrupt protease acitvity; (ii) prevent zymogen processing; (iii) prevent substrate binding; and (iv) alter immunoreactivity." The Applicants point out that the mutagenesis scheme is not limiting for the creation of cysteine proteases with only single mutations, as it broadly describes the genus. Cysteine proteases with a combination of mutations are encompassed by the mutagenesis technique, because variants with a combination of mutations may share the same functional characteristics which define the genus. The instant application provides adequate support for the description of mutated cysteine proteases with a combination of mutations. It is easy for one with skill in the art to envision that cysteine proteases with a combination of amino acid substitutions, where each single substitution disrupts cysteine proteases activity, share the same disrupted activity when combined with each other. Additionally, it is well within the ability of one with ordinary skill in the art to envision that any amino acid substitution in a cysteine protease with an existing mutation in the catalytic site preserve the characteristics of the mutated cysteine proteases described by the genus. The Applicants contend that the arguments above identify said claims as being adequately supported by the original specification, and as such, cannot constitute new matter. Thus, the Applicants request that the rejection of claims 20-35, and 45-47 on the grounds that they constitute new matter be withdrawn.

III. Claims 1, 4-35, 45-47 are enabled.

The Examiner has rejected claims 1, 4-35, 45-47 on the grounds that they are not adequately enabled by the specification. The Examiner asserts that the claims are drawn to a vaccine and method of immunizing, which are not enabled by the specification. Additionally, the Examiner contends that the use of mutated cysteine proteases, comprising at least one amino acid substitution, are not enabled as to being able to confer immunity. Applicants respectfully traverse.

Applicants have amended claims 1, 4-7, 9, 11, 13, 15, 17, 18, 20, 22, 24-29, 45, and

46 without prejudice and without acquiescence in order to advance the prosecution of the present application. The amendments remove the language that the Examiner maintains is not enabled. The Examiner specifically states that vaccines or protective immunity are not enabled. Thus, in light of the above amendments, Applicants respectfully request that the 35 U.S.C. § 112, first paragraph rejection be withdrawn.

Conclusion

Claims 1, 4-35, 45-47 are pending in this application. Claims 36-44 have been withdrawn because they are to a non-elected invention. Applicants retain the right to file a divisional application to any cancelled or withdrawn claims. Claims 1, 4-7, 9, 11, 13, 15, 17, 18, 20, 22, 24-29, 45, and 46 have been amended to clarify the scope of the claims. Accompanying this paper, Applicants are also submitting formal drawings.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P00965US0 from which the undersigned is authorized to draw.

Dated: October 30, 2002

Respectfully submitted,

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